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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,272

04/17/2006

Dariusz Behnam

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

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09/15/2009

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/576,272	<b>Applicant(s)</b> BEHNAM, DARIUSH	
	<b>Examiner</b> JENNIFER M. KIM	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/6/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Claims 1-14 are presented for examination.**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "approximately 75 weight-percent to approximately 85 weight-percent of polysorbate" in lines 3-4 is not clear whether the range is the respect to the content of the polysorbate with respect to the composition. In the specification page 1, last full paragraph, states that "approximately 75 weight-percent to approximately 85 weight-percent of polysorbate has proven itself". It is therefore, unclear what is intended.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 7, 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Peters et al. (U.S. Patent No. 6,455,072 B1).

Peters et al. teach a stable aqueous particulate suspension consisting essentially of lutein and polysorbate 80. (column 4, claim 2). Peters et al. teach that the amount of nutrients such as lutein is from 0.005 parts by weight to about 10 parts by weight based on 100 parts by weight of the dispersion. (column 2, lines 19-23). Peters et al. teach that the amount of stabilizer such as polysorbate 80 can be present in a formulation is from about 0.05 percent by weight to about 10 percent by weight. (column 3, lines 15-22). This amount touches Applicants amounts set forth in claims 1 and 7).

With regard to the method of manufacturing claims set forth in claims 9-14, it is well settled in patent law that product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. See MPEP § 2123. The court in In re Thorpe held, “even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” See 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. (U.S. Patent No. 6,455,072 B1).

Peters et al. teach a stable aqueous particulate suspension consisting essentially of lutein, polysorbate 80 and an **aqueous solvent system**. (column 4, claim 2). Peters et al. teach that **water** is an example of the aqueous system. (column 3, lines 25-27).

Peters et al. teach that the amount of nutrients such as lutein is from 0.005 parts by weight to about 10 parts by weight based on 100 parts by weight of the dispersion. (column 2, lines 19-23). Peters et al. teach that the amount of stabilizer such as polysorbate 80 can be present in a formulation is from about 0.05 percent by weight to about 10 percent by weight. (column 3, lines 15-22). This amount touches and is within Applicants amounts set forth in claims 1 and 7. Peters et al. teach that amount of

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additives in associated with therapeutic treatment depend from its desired nutritional or therapeutic effect. (column 2, lines 5-23).

Peters et al. do not expressly teach the specific amount of water set forth in claim 6 and the origin of lutein obtained set forth in claim 5.

It would have been obvious to one of ordinary skill in the art to optimize the water content of the stable aqueous suspension of Peters et al. because Peters et al. teach that an aqueous solvent system comprising lutein and polysorbate results in stable aqueous system and that the amount of additives such as water can be employed in varying amounts depends on its desired effect. One would be motivated to optimize the amount of water in Peters et al's suspension in order to achieve a stable aqueous suspension in a composition comprising lutein, polysorbate and aqueous system, namely, water. Further, the amounts of active agents (polysorbate) to be used, the pharmaceutical forms, e.g., tablets, etc; mode of administration, flavors, surfactant are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration.

Claims 4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. (U.S.Patent No. 6,455,072 B1) in view of Matsuda et al. (U.S.Patent No. 5,180,747).

Peters et al. as applied as before. Additionally, Peters et al. teach that a nutrient stabilizer in an amount effective to stabilize the active agent can be employed as an aqueous dispersion. (column 2, lines 65-column 3, lines 5).

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Peters et al. do not expressly teach the composition further comprising moderate-length-chain triglyceride and its amount and zeaxanthin and their amounts set forth in claims 4 and 8.

Matsuda et al. teach that zeaxanthin is useful stabilizer for the fat-soluble vitamin composition comprising Co-enzyme Q. (abstract, column 1, lines 45-55, column 2, lines 3-10). Matsuda et al. teach the composition can be formulated as a solution comprising fat-soluble vitamins (Coenzyme Q), carotenoids (zeaxanthin), water and oil component such as a medium-chain fatty acid triglyceride (MCT). (column 1, lines 50-55, column 2, lines 2-36).

It would have been obvious to one of ordinary skill in the art to incorporate a stabilizer such as zeaxanthin and oils such as MCT to Peters et al's composition because Matsuda et al. teach that zeaxanthin stabilizes fat soluble vitamin (Co-enzyme Q10) composition and that MCT is routinely added together with zeaxanthin to stabilize the composition. One would have been motivated to make such a modification in order to achieve expected benefit of zeaxanthin well known by Matsuda et al. to stabilize fat-soluble vitamin in a nutritional formulation.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

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### **Communication**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/  
Primary Examiner, Art Unit 1617

Jmk  
September 14, 2009



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